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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,542	03/02/2004	Vinay G. Sakhrani	5764-001	3383
24112	7590	03/21/2008		
COATS & BENNETT, PLLC 1400 Crescent Green, Suite 300 Cary, NC 27518				
EXAMINER				
ZACHARIA, RAMSEY E				
ART UNIT		PAPER NUMBER		
1794				
MAIL DATE		DELIVERY MODE		
03/21/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/791,542

Applicant(s)

SAKHRANI ET AL.

Examiner

Ramsey Zacharia

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 14, 15, 17-28, 30 and 32-39 is/are pending in the application.
- 4a) Of the above claim(s) 1-9 and 19-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-12, 14, 15, 17, 18, 25-28, 30 and 32-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

2. Claims 1-9 and 19-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 27 February 2006.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 36 and 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection because no support could be found in the disclosure as originally filed for a syringe comprising a barrel made of a cyclic olefin polymer or cyclic olefin copolymer.

Claim Rejections - 35 USC § 103

5. Claims 10-12, 14, 15, 17, 18, 25-28, 30, 32-35, 38, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al. (U.S. Patent 4,822,632) in view of Murayama et al. (US 5,830,577).

Williams et al. teach a surface coated with a lubricant wherein at least one of the surface and the lubricant is treated with an ionizing plasma and the lubricant is applied to at least one surface prior to or subsequent to the application of plasma (column 2, lines 34-41). That is, the surface and/or deposited lubricant are treated with ionizing plasma. The preferred lubricant is a synthetic oil, such as a silicone (column 3, lines 47-48). The surface to be treated may be the barrel of a syringe (column 2, lines 62-66). The plasma may be generated from a variety of gasses, such as air, hydrogen, helium, etc. and performed at any pressure (column 4, lines 12-24). The lubricant may be applied neat or in a solvent with the subsequent removal of the solvent by evaporation (column 3, lines 63-65). Suitable materials to which the lubricant may be applied include glass and plastics, such as polypropylene (column 3, lines 22-38).

Regarding the limitation that the lubricant is exposed to an energy source at atmospheric pressure, one skilled in the art would readily envisage atmospheric pressure because Williams et al. teach that any pressure can be used. Alternatively, it would have been obvious to one skilled in the art to conduct the plasma treatment at atmospheric pressure since Williams et al. explicitly teach that any pressure may be used.

Williams et al. do not teach the use of a one of the fluorochemicals in the Markush groups recited in instant claims 10 and 25. However, Williams et al. do teach that synthetic oils are the preferred lubricants and cites silicone oil as a suitable lubricant.

Murayama et al. is directed to lubricants which function at an interface subjected to a sliding contact (column 1, lines 9-12). The lubricant is designed to reducing the static friction coefficient (column 1, lines 36-47), i.e. reduce the forces required for breakout of surfaces from stationary contact into sliding contact. Suitable lubricants include perfluoropolyethers and silicone oil (column 5, lines 34-45).

Murayama et al. show that perfluoropolyethers and silicone oils are known in the art as an equivalent lubricants for reducing static friction. Therefore, because these two lubricants were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute a perfluoropolyethers for the silicone taught by Williams et al. See MPEP 2144.06.

Moreover, because the perfluoropolyether lubricant disclosed by Murayama et al. is taught to reduce static friction, it would have been obvious to use the perfluoropolyether lubricant as the synthetic oil of Williams et al. since it has been held that the selection of a known material based on its suitability for its intended use supported a *prima facie* obviousness determination. See MPEP 2144.07.

6. Claims 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al. (U.S. Patent 4,822,632) in view of Murayama et al. (US 5,830,577) as applied to claim 33 above, and further in view of Sudo et al. (US 6,090,081).

Williams et al. taken in view of Murayama et al. teach all the limitations of claims 36 and 37, as outlined above, except for the use of a cyclic olefin polymer or copolymer as the material for the syringe barrel. However, Williams et al. is directed to coating syringe barrels and cite

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glass and plastics, such as polystyrene, as suitable materials to which their coating may be applied.

Sudo et al. disclose that it is known in the art to fabricate syringe barrels out of plastics, such as polystyrene, cyclic olefin resins, and cyclic olefin-ethylene copolymer (column 9, lines 40-49).

That is, Sudo et al. show that polystyrene, cyclic olefin resins, and cyclic olefin-ethylene copolymer are known in the art as functionally equivalent materials for fabricating syringe barrels. Therefore, because these plastics were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute cyclic olefin resins or cyclic olefin-ethylene copolymer for polystyrene.

It would further be obvious to one skilled in the art to use a cyclic olefin resin or cyclic olefin-ethylene copolymer for the barrel of the syringe since it has been held that the selection of a known material (e.g. cyclic olefin resins or cyclic olefin-ethylene copolymer) based on its suitability for its intended use (syringe barrel) supported a *prima facie* obviousness determination. See MPEP 2144.07.

Response to Arguments

7. Applicant's arguments filed 28 December 2007 with respect to the rejection over Williams et al. in view of Murayama et al. have been fully considered but they are not persuasive for the following reasons.

The applicants argue that, since Murayama et al. teach that the lubricant is bound to the host molecule and not the surface, one skilled in the art would understand that in order to bind a

perfluoropolyether to a surface, a host compound would be required and the surface must include acidic functional groups.

This is not persuasive since Murayama et al. also teach the use of a silicone oil lubricant and it would be clear to one skilled in the art from Williams et al. that a host compound and surface with acidic functional groups is not required to bind a lubricating silicone compound to the surface. As such, one skilled in the art would recognize that lubricants may be bound to surfaces by several different mechanisms (e.g. those taught by Williams et al. as well as those taught by Murayama et al.). Moreover, since the teachings of Murayama et al. illustrate that both silicone oil and perfluoropolyethers may be used as lubricants to reduce the static friction coefficient, it would have been obvious to one skilled in the art to use a perfluoropolyether in place of silicone oil in the application of Williams et al., particularly since Williams et al. teach the use of a "synthetic oil" as their lubricant. It is also noted that there is additional motivation for one skilled in the art to use perfluoropolyether as the synthetic oil lubricant of Williams et al. since it has been held that the selection of a known material (e.g. perfluoropolyether) based on its suitability for its intended use (e.g. lubricant for reducing the static friction coefficient) supported a *prima facie* obviousness determination.

The applicants argue that Williams et al. teach against the use of a fluorochemical, citing column 2, lines 18-25 for support. However, this is not persuasive since this passage is discussing the conventional use of a polytetrafluoroethylene surface, and not fluorochemical compounds in general nor perfluoropolyethers in particular, and is not directed to surfaces or lubricants that have been treated with ionizing plasma as required by the teachings of Williams et al.

The applicants argue that the phrase "any pressure" only invites those of skill in the art to try pressures within the scope of the teachings and the scope of the teachings is only directed to ionizing gas plasmas produced under conditions of extreme vacuum.

This is not persuasive for the following reasons. First, one skilled in the art would recognize that "any pressure" means any pressure. Second, the teaching of a preferred embodiment (e.g. "gas pressures are advantageously maintained at 5 mm of Hg or below") does not constitute a teaching away from a broader disclosure (e.g. "any pressure") or nonpreferred embodiments. See MPEP 2123.

Response to Amendment

8. The declaration under 37 CFR 1.132 filed 28 December 2007 is insufficient to overcome the rejection of the claims based upon Williams et al. in view of Murayama et al. as set forth in the last Office action for the following reasons.

First, the declaration does not spell out the time or power under which the plasma was applied for Examples B, E, F, and G. Without knowing how long or at what power the atmospheric plasma was applied, it is impossible to know whether the effects reported are a result of the pressure at which the plasma applied or the result of some other variable.

Second, the claims are not commensurate in scope with the showings presented in the declaration. In each example of the invention presented in the declaration, a perfluoropolyether was used as the lubricant. This is in contrast to independent claims 10 and 25 which do not limit the lubricant to a perfluoropolyether but also permit the use of polychlorotrifluoroethylene. Additionally, each of the example of the invention presented in the declaration uses plasma as

the energy source while independent claim 10 recites an ionizing radiation that is not limited to plasma. As such, the declaration is insufficient to overcome the rejection, since it has been held that the objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support (see MPEP 716.02(d)).

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ramsey Zacharia whose telephone number is (571) 272-1518. The examiner can normally be reached on Monday through Friday from 9 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rena Dye, can be reached at (571) 272-3186. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Ramsey Zacharia/

Primary Examiner, Art Unit 1794